

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

JUDY WETHINGTON, et al.,	:	Case No. C-1-01-441
	:	
Plaintiffs,	:	Judge Spiegel
	:	
vs.	:	
	:	
PURDUE PHARMA, L. P., et al.,	:	
	:	
Defendants.	:	

**PLAINTIFFS' OPPOSITION MEMORANDUM IN RESPONSE TO
PURDUE DEFENDANTS' MOTION TO STRIKE EXHIBIT "A" TO
PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO
RECONSIDER AND SUBMISSION OF NEW AUTHORITY**

INTRODUCTION AND BACKGROUND

When this Court initially denied Plaintiffs' motion for class certification, it found that individual issues existed that precluded certification. Although Plaintiffs disagree with this finding, Plaintiffs also believe that recent events demonstrate that broader common issues are present than existed when this Court issued its Opinion. Those new issues involve findings by the United States Drug Enforcement Agency and new litigation involving allegations from a former key Purdue scientist--Marek Zakrzewski, Ph.D.-- that Purdue intentionally hid from the United States Food and Drug Administration and the medical community that OxyContin contained important flaws that could contribute and exacerbate the

drug's addictive potential and contribute and exacerbate its abuse potential.

Plaintiffs submitted this information by filing the whistle blower complaint that Dr. Zakrzewski filed against Purdue. In Plaintiffs' reply memorandum, Plaintiffs included Dr. Zakrezewski's amended complaint.

Purdue responded to Plaintiffs' submission of the Zakrezewski Complaints by submitting the affidavit of Glenn Van Buskirk, Ph.D. The Van Buskirk affidavit seeks to respond to the merits of Zakrzewski's factual statements.

During the pendency of Plaintiffs' motion for reconsideration, additional events have occurred that demonstrate that Purdue has made intentional misrepresentations to Federal Agencies and withheld information from the Government. The United States District Court for the Southern District of New York, for example, on January 5, 2003 issued an Order and Opinion in the patent litigation between Purdue and Endo Pharmaceuticals, Inc. *See Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*, Case No. 01 Civ. 8029 (S.D. New York, January 5, 2004). A copy of the Opinion is attached as Exhibit "A". In the Order, the Court found that Purdue made intentional and material misrepresentations to the United States Patent Office when Purdue received a patent for OxyContin. According to the Court, the "record as a whole reflects a clear pattern of intentional misrepresentation of a material fact-Purdue knew that it did not have 'scientific proof' of its 'discovery,' yet repeatedly asserted its 'discovery' to the PTO in

precise, quantified, past-tense language.” Order at 48. The Court concluded that “Purdue committed inequitable conduct before the PTO during the prosecution of the... patents, the patents in suit...are rendered unenforceable.” *Id* at 49.

In addition to the adverse patent decision in January of 2004, additional facts have developed that demonstrate that Purdue engaged in deceptive conduct when it withheld marketing material from the United States Food and Drug Administration. In December of 2003, the United States General Accounting Office issued A Report to Congress: OxyContin Abuse Diversion and Efforts to Address the Problem. A copy of the relevant portions of the GAO Report are attached as Exhibit “B”. In the Report, the GAO found that Purdue provided two promotional videos to physicians that appear to have made unsubstantiated claims and minimized the risks of OxyContin. Report at page 17, 27-28. The GAO’s findings and Report was unavailable to the parties when the Court denied Plaintiffs’ Motion for Class Certification. The GAO Report describes how Purdue violated federal regulations when it failed to produce the videos to the FDA.

FDA regulations require pharmaceutical manufacturers to submit all promotional materials for approved prescription drug products to the agency at the time of their initial use. Because Purdue did not comply with this regulation, FDA did not have an opportunity to review the video to ensure that the information it contained was truthful, balanced, and accurately communicated.

GAO Report at 27. Attached as Exhibit “B”.

The GAO's findings together with the other recently disclosed developments reveal that Defendants engaged in deceptive and manipulative conduct. Defendants intended the unlawful conduct to cause the medical community to prescribe overpriced and potentially dangerous medication to members of the class. Unfortunately, the Defendants succeeded.

ARGUMENT

I. The Court should consider the Zakrzewski Complaint, the Patent Order and the GAO Report when reviewing Plaintiffs' motion to reconsider the denial of class certification.

A. The Court properly may consider the Zakrzewski complaints

The law is clear that the Court cannot base its class certification decision on the merits of Plaintiffs' claims. *See Eisen v. Carlisle & Jacqueline*, 417 U.S. 156 (1974). The Court when determining whether to certify a class action is entitled to consider a well pleaded complaint. *See Davis v. Avco Corp.*, 371 F. Supp. 782, 790 (N.D. Ohio 1974). Thus, typical evidentiary matters are not dispositive in the context of a class certification motion where the primary concern is whether the Plaintiffs satisfy the requirements of Rule 23.

In this case, the court clearly should consider the Zakrzewski complaints and deny Purdue's invitation to strike the complaints. The Zakrzewski complaints demonstrate that important issues exist concerning Defendants' design of OxyContin and Defendants' manufacturing practices. Defendants, by choosing to

challenge the Zakrzewski complaints with the affidavit of Glenn Van Buskirk, at a minimum, implicitly acknowledge the Zakrzewski complaints raise important common issues. By submitting the affidavit, Purdue is asking the court to decide the merits of Dr. Zakrzewski's charges¹. Clearly, the court cannot decide these common issues at this stage of the proceedings. Thus, the Zakrzewski complaints and Purdue's response reveal that the appropriate course for the Court to take is to certify the class and decide the merits created by the common issues at the appropriate time.

The law referenced by Purdue fails to suggest a different result. The authorities cited do not involve class certification. To the contrary, the unpublished *Broome* decision involved a wrongful death action. *See Broome v. Dazey Corp.*, 1989 WL 109443. The *Broome* Opinion, moreover, suggests that the trial court has discretion when considering matters related to the relevance of a complaint. *Id.* at **3. ² Purdue's submission of *Foister v. Purdue Pharma L.P.*, Case No. 6:01-268-DCR (December 30, 2003, E.D. Ky), similarly does not apply to issues related to class certification. The recent *Foister* Opinion involved merits issues related to summary judgment involving individual plaintiffs. The record in *Foister* obviously

¹ Plaintiffs understand that the Zakrzewski whistle blower litigation is proceeding. To date, Defendants have failed to obtain a dismissal.

² Although not relevant in the context of class certification, Purdue is wrong when it asserts as a matter of law that a complaint cannot serve as evidence. See *Schroeder v. McDonald*, 55 F.3d 454, 460 (9th Cir. 1995).

is different than the record in this case. Indeed, the consideration of summary judgment in this case is premature. Plaintiffs have not had the opportunity to conduct full merits discovery. Thus, the *Foister* Opinion is of little help to the Court when it decides whether recent events, apparently unknown to the *Foister* Court, merit reconsideration of the Court's denial of class certification.

B. The Patent Order demonstrates that common issues exist concerning Plaintiffs' Consumer Protection allegations

Plaintiffs' Second Amended Complaint alleges in the Sixth Cause of Action that Defendants violated State Consumer Protection Laws. The recent Patent Decision against Purdue demonstrates that Purdue engaged in fraudulent conduct before a Federal Agency for the purpose of receiving the exclusive right to sell and market OxyContin. By acquiring the exclusive right through fraudulent activities, Purdue violated the consumer protection laws in the states of Ohio, West Virginia, Kentucky, and Indiana. Indeed, by acquiring the exclusive right through unconscionable means to sell OxyContin, Purdue succeeded in securing unreasonable profits and forcing members of the class to pay inflated prices for their medication. Under these circumstances, class certification is appropriate. *See Delahunt v. Cytodyne Technologies*, 241 F.Supp 2d 827, 838-39 (S.D. Ohio 2003) (unconscionable conduct in the sale of dietary supplements suggests the existence of class wide issues).

C. The GAO report demonstrates that common issues exist regarding Defendants' manipulation of information to the medical community

Defendants repeatedly have asserted that FDA oversight immunizes them from liability. To the extent that this defense is viable³, the defense is contingent on Defendants compliance with FDA rules and regulations. The recent GAO revelations reveal that Purdue withheld important materials from the FDA. Thus, the FDA was unable to determine whether Defendants properly performed their obligation to educate the medical community concerning the dangers of OxyContin. Indeed, Defendants had a self-serving reason to withhold the information from the FDA. When it finally reviewed the materials, the FDA found that the materials “ made unsubstantiated claims and minimized the risks of OxyContin.” GAO Report at 17.

³ Plaintiffs challenge this defense and do not accept FDA approval as a complete defense to liability.

CONCLUSION

For the reasons contained in this Memorandum, the Court should refuse Purdue's request to strike the Zakrezwski Complaints and should reconsider its previous denial of Plaintiffs' request for class certification.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a copy of Plaintiff Wethington's Opposition Memorandum to Purdue Defendants' Motion to strike Exhibit "A" attached to Plaintiffs' Reply Memorandum in Support of Motion for Reconsideration was served by regular United States mail; postage prepaid and by Electronic Service on the following counsel for Defendants this 4th day February 2004:

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